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Atty. Docket No. P71140US0

IN THE SPECIFICATION:

For the purposes of line numbers referred to herein, lines of text as well as blank lines between paragraphs are counted. Accordingly, beginning the numbering with the first line of the text after the title, the second paragraph on page 1, for example, is designated herein as beginning at line 6 of the text as originally filed, the second full paragraph on page 2 begins at line 15 of the text as originally filed, and so on.

On page 1, please delete all of the text appearing before the title of the invention.

On page 1, before line 1 of the text and after the title, please insert the following headings:

--BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION--.

On page 1, please amend the first paragraph beginning on line 1, as follows:

--~~This~~ The present invention relates to a connector for connecting a dialysate port of a ~~hemodialysis machine~~ dialyzer to

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a dialysate-carrying line ~~according to the preamble of Claim 1~~ with a first lumen and a second lumen passing through the connector, a first end of the connector surrounding the first lumen, suitable for accommodating the dialysate port in the first lumen, a second end of the connector surrounding the second lumen and suitable for being connected to the dialysate-carrying line.--

On page 1, line 5, please insert the following heading:

--2. DESCRIPTION OF THE RELATED ART--.

On page 1, please amend the text beginning on line 6, through line 16 on page 3, as follows:

--During a hemodialysis treatment, blood is taken from a patient with the help of an extracorporeal circulation and is passed through a ~~hemodialysis machine~~ dialyzer. Such ~~dialysis machines~~ dialyzers today consist of a bundle of thousands of semipermeable hollow fiber membranes through the interior of which the blood is passed. A cleaning fluid--the dialysis fluid or the dialysate--is circulated on the outside of the hollow fibers so that the substances to be removed from the blood enter this fluid by diffusion and/or convection.

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Such a ~~hemodialysis machine~~ dialyzer generally has four liquid connections, which are known as ports: two for blood and two for the dialysate. The tubing system of the extracorporeal blood circulation and the dialysate-carrying line system in the sense of one incoming line and one-outgoing line is connected to these ports. For the purpose of uniformity in use, standardized port forms are used for the blood ports on the one hand and for the dialysate ports on the other hand. Although the connecting system for the blood tubing system is designed to work with disposable items, the tubing used for the lines carrying the dialysate with many ~~hemodialysis machines~~ dialyzers for treatment of chronic renal insufficiency is reusable. The Hansen coupling, as it is called, is used as the connecting system. With the Hansen coupling, the connection to the dialysate port is locked by a metallic ball bearing element. According to DIN 58352, a German standard, the dialysate port consists of an essentially tubular projection having a peripheral undercut upstream from the end of the port in the sense of a reduced outside diameter in which the balls of the ball bearing element engage. Between individual treatments, the dialysate-carrying lines are rinsed and cleaned together with the remaining dialysate circulation.

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However, with other ~~hemodialysis machines~~ dialyzers, disposable tube sets are also used for the dialysate-carrying lines. In this case it is expedient to use a design different from the Hansen coupling for the corresponding connector, in particular when the connector is also a disposable part.

EP 0 442 310 A1 describes ~~dialysis machine~~ dialyzer ports of a ~~hemodialysis machine~~ dialyzer which allow connection of Hansen couplings as well as other connectors. To this end, the ~~dialysis machine~~ dialyzer port is provided with a thread onto which a corresponding connector mating piece can be screwed.

A screwing motion to establish the connection is a disadvantage inasmuch as it is difficult to determine the endpoint of the screwing motion. Leakage may occur if the connector is not screwed on adequately, while on the other hand, if too much force is applied to the end of the connector, it may quickly result in damage to the sealing elements, which are generally provided in these connectors. In addition, this connector may be used only when the ports on the ~~dialysis machines~~ dialyzers are also designed accordingly, i.e., design measures are also required on the mating piece of the connector.

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#### SUMMARY OF THE INVENTION

The object of ~~this~~ the present invention is to improve upon a generic connector, so that it can be manufactured suitably as a disposable item while at the same time permitting simple and reliable connection of a dialysate-carrying line to a dialysate port of a ~~hemodialysis machine~~ dialyzer without requiring structural measures on the ~~dialysis machine~~ dialyzer itself.

According to the teaching of this invention, this object is achieved by a connector ~~having the features of Claim 1 for~~ connecting a dialysate port of a dialyzer having a dialysate-carrying line with a first lumen and a second lumen passing through the connector, the first end of the connector surrounding the first lumen and suitable for accommodating the dialysate port in the first lumen. The second end of the connector surround the second lumen and is suitable for being connected to the dialysate-carrying line. A recess with a shift element accommodated therein is provided on the first end, whereby the shift element is displaceable between a first position and a second position perpendicular to the direction of the first lumen in the first end of the connector. In the first position, the shift element does not penetrate through the first lumen and, in the

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second position, the shift element narrows the first lumen so that the connector with the shift element is placed on the dialysate port in the first position and in the second position it can be locked on the dialysate port by means of an undercut thereon.  
~~Design embodiments of this invention are the object of the subclaims.~~

According to one design embodiment, the connector includes not only the shift element but also a base body which is composed of two interconnected essentially cylindrical sleeves whereby the first sleeve is the first end and the second sleeve is the second end. Preferably, the outside diameter of the first sleeve is greater than the outside diameter of the second sleeve, and the first sleeve is suitable for accommodating a port according to DIN 58352.

Further, the first lumen in the first sleeve can have a larger diameter than the second lumen in the second sleeve. The connector can also be provided with a stop for the dialyzer port in the connecting area of the two sleeves. In addition a sealing element may be provided on the inside wall of the first sleeve near the stop for sealing the connector with respect to the dialyzer port.

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According to another embodiment, the connector includes a constriction area in the first and second lumens between the first and second ends of the connector.

In addition, the recess may include two opposite recesses. In this case, the shift element has a first opening which does not constrict the first lumen in the first position and has a second opening which is connected to the first opening in the direction of shifting and which constricts the first lumen in the direction of the opposite recesses in the second position. The first opening can have a round shape and the second opening can have an elongated shape so that the overall shape is that of a keyhole. Further, the first opening can have catch projections which can engage with complementary recesses on the first end of the connector for the purpose of engaging the shift element in the first position. These complementary recesses may be additionally provided symmetrically on the first end of the connector on the opposite side of the first lumen in the direction of shifting.

According to a further embodiment, the second opening is provided with an expanded opening area perpendicular to the direction of shifting for accommodating the dialyzer port for engagement of the shift element in the second position. The

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elongated border of the second opening can have a wall thickness that tapers with a slope toward the opening and can have a form-fitting engagement with a corresponding slope on the undercut of the dialyzer port.

This invention is based on the observation that the dialysate port designed according to German standard DIN 58352 has a peripheral undercut on the outside. This undercut can be used for a shift element that is provided on the connector designed according to this invention for locking the connector. In this case it is not necessary to redesign the port on the ~~dialysis machine~~ dialyzer end.--

On page 3, line 17, insert the following heading,  
--BRIEF DESCRIPTION OF THE DRAWINGS--.

On page 3, line 34, insert the following heading along with the new paragraph following thereafter:

--DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Further scope of applicability of the present invention will become apparent from the detailed description given hereinafter. However, it should be understood that the detailed



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description and specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.--.

On page 3, please amend the paragraph beginning on line 35, as follows:

--Fig. 1 shows an embodiment of the inventive connector 1 for connecting a dialysate port of a ~~hemodialysis machine~~ dialyzer to a dialysate-carrying line (not shown) in a side view. The connector 1 consists of a base body 2 and a shift element 3. The base body 2 is composed of a first cylindrical sleeve 4, which is situated on the first end of the connector 1 that is to be connected to the ~~dialysis machine~~ dialyzer port, and a second cylindrical sleeve 5, which is situated on the second end of the connector 1 that is to be connected to the dialysate-carrying line. The outside diameter of the first sleeve is greater than the outside diameter of the second sleeve, which is determined by the dimensions of the lines to be connected. The two sleeves have a fluid-tight connection in a connecting area 7, as shown in Figs. 3a

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and 3b. A lumen (not shown in Fig. 1) extends through the base body of the connector, and in the case of the connection, some of the dialysate flows through this lumen, and for the remainder, it accommodates the dialysate port of the ~~dialysis machine~~ dialyzer.--

On page 5, please amend the paragraph beginning on line 28, as follows:

--An enlarged opening area 14 and 14' is provided in the second opening 10, running concentric with the lumen 8 when the shift element is in the second position (Fig. 2b). In this position the second opening 10 constricts the lumen 8 in the direction of the recesses 6 and 6'. The contours of the opening areas 14 and 14' conform to those of the dialysate port of the dialyzer ~~hemodialysis machine~~. Due to the slightly restricted width of the opening 10 directly next to the, regions 14 and 14', the shift element 3 is also held in the second position--with the dialysate port inserted (not shown in Fig. 2b).--

On page 7, please amend the paragraph beginning on line 18, as follows:

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--With the shift element 3 in the first position, the inventive connector can be pushed onto to the dialysate port. The connector 1 is then locked by shifting the shift element 3 into the second position (Fig. 3b). The shift element 3 then engages behind the undercut 30, which is designed as a peripheral groove and is provided in the dialysate port 31. The dialysate port 31 is part of a ~~dialysis machine~~ dialyzer housing 32.--

On page 8, please amend the last paragraph as follows:

--The inventive connector permits a connection of a dialysate-carrying line to a conventional port of a ~~hemodialysis machine~~ dialyzer which is easy and reliable to handle. Only a few individual parts are required, and those may be manufactured inexpensively from plastics by the injection molding technique. The connector may also be used with other ports whose connections can be inserted into the first end of the connector and which have an undercut that can be gripped with the help of the shift element for the purpose of locking. This is true in particular of all ports according to DIN 58352.--

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On page 8, after the last line, please insert the following paragraph:

--The invention being thus described, it will be apparent that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention, and all such modifications as would be recognized by one skilled in the art are intended to be included within the scope of the following claims.--.